



**Office of Human Subjects Research
Institutional Review Boards**

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmeirb@jhmi.edu

Date: June 14, 2017

CONTINUING REVIEW APPROVAL

Review Type: Expedited
Principal Investigator: Steven Frank
Number: NA_00078426 / CR00016216
Title: Database Review to Assess Blood and Blood Product Utilization at The Johns Hopkins Hospital
Committee Chair: Susan Bassett
IRB Committee: IRB-X

Date of approval: June 14, 2017

Date of Expiration: June 13, 2018

The JHM IRB approved the above-referenced Continuing Review.

Retrospective Chart Review/Existing Specimens Only/Data collection ongoing.

45CFR46.404 and/or 21 CFR 50.51: This study has been approved for the inclusion of children as 'research not involving greater than minimal risk'. The permission of parents/guardians is waived.

If this study is a clinical trial and data collection is complete for the prespecified primary outcome, Section 801 of the Food and Drug Administration Amendments Act requires reporting of summary results information at <http://www.clinicaltrials.gov>. Reporting must be done within 12 months of completing data collection for the prespecified primary outcome, regardless of sponsor or funding source. Failure to comply with this law may result in civil penalties. For more information on results reporting go to <http://www.clinicaltrials.gov>. If the study is registered with Clinicaltrials.gov and is closed to recruitment and enrollment, the record must be updated within 30 days to reflect the study's enrollment status. See <http://clinicaltrials.gov/ct2/manage-recs/how-edit> for more information. Questions can be directed to register@clinicaltrials.gov.

Date of Approval and Expiration Date: The approval and expiration date for this research are listed above. If the approval lapses, the research must stop and you must submit a request to the IRB to determine whether it is in the best interests of individual participants to continue with protocol-related procedures.

Changes in Research: All proposed changes to the research must be submitted using a Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Continuing Review: Continuing Review Applications should be submitted at least 6 weeks prior to the study expiration date. Failure to allow sufficient time for review may result in a lapse of approval. If the Continuing Review Application is not submitted prior to the expiration date, your study will be terminated and a New Application must be submitted to reinitiate the research.

Unanticipated Problems: All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

The Johns Hopkins Institutions operates under multiple Federal-Wide Assurances: The Johns Hopkins University School of Medicine - FWA00005752, The Johns Hopkins University School of Nursing - FWA00006088, The Johns Hopkins Hospital and Johns Hopkins Health Systems - FWA00006087, Johns Hopkins Bayview Medical Center - FWA00006089, Howard County General Hospital - FWA00005743, Hugo W. Moser Research Institute at Kennedy Krieger, Inc. - FWA00005719, Johns Hopkins Community Physicians - FWA00002251, Suburban Hospital and Health System - FWA00005924